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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/625,754	07/23/2003	Steven M. Leventer	JAN-027 CON	8132

7590 03/29/2005  
Vela Pharmaceuticals  
3528 Old Baptist Rd.  
Collegeville, PA 19426

EXAMINER
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HENLEY III, RAYMOND J

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 03/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/625,754	<b>Applicant(s)</b> LEVENTER ET AL	
	<b>Examiner</b> Raymond J. Henley III	<b>Art Unit</b> 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on February 14, 2005.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-5 and 28-32 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5 and 29 is/are rejected.
- 7) ☒ Claim(s) 30-32 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

**CLAIMS 1-5 AND 28-32 ARE PRESENTED FOR EXAMINATION**

Applicants' amendment and Terminal Disclaimers filed October 25, 2004, amendment filed December 2, 2004 and amendment filed February 14, 2005 have been received. Due to the informalities contained therein, the amendments filed October 25, 2004 and December 2, 2004 were not entered into the application.

The amendment filed February 14, 2005 and Terminal Disclaimers filed October 25, 2004 have been entered into the application. Accordingly, claims 1-5 and 28-32 have been amended.

In view of the acceptable nature of the Terminal Disclaimers, the provisional rejection of claims 1-5 and 28-32 under the judicially created doctrine of obviousness-type double patenting over claim 31 of co-pending Application No. 10/781,422 and the actual rejection of claims 1-5 and 28-32 under the judicially created doctrine of obviousness-type double patenting over claims 1-5 of U.S. Patent No. 6,649,607, as set forth in the previous Office action dated August 16, 2004 at pages 4-5, are withdrawn.

Also, in light of the amendment to claim 32, the objection thereto, as set forth in the previous Office action dated August 16, 2004 at pages 2-3, is withdrawn.

***Specification***

The disclosure remains objected to because "This application is a continuation of application Serial No. 10/008,516, filed November 8, 2001, now U.S. Patent No. 6,649,607" has not been added to the first page of the specification.

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It is noted that Applicants presented an amendment to the specification in the papers filed October 25, 2004 which would have overcome this objection. However, because of the informality of the amendment, it was not entered into the application and the proposed change to the specification was not present in the most recently filed amendment, i.e., the amendment filed February 14, 2005. Accordingly, the objection remains proper.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-5, 28 and 29 remain rejected under 35 U.S.C. 102(a) as being anticipated by Landry et al. (U.S. Patent No. 6,080,736), already of record, for the reasons of record as set forth in the previous Office action dated August 16, 2004, at pages 3-4.

Applicants' amendments to the claims, i.e., inserting the term "pharmaceutical" before "composition" at line 1, and arguments at pages 8-9 of the most recently filed amendment have been carefully considered, but fail to persuade the Examiner of error in his determination.

In particular, while it is noted that the composition taught by Landry et al. is not taught for a therapeutic purpose because it was found that the S-isomer of tofisopam was not effective for the purposes sought, this does not provide a patentable distinction.

In particular, that the composition was not found suitable for the patentees' purposes fails to render the composition taught thereby, i.e., a composition that comprises 95%+ pure S-tofisopam (col. 20, line 61-62), 2% tween and 5% DMSO and distilled water (Table 1 at col. 20),

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non-existent. Whether reported as being effective or not, the clear teaching of the patentees of the existence of this composition precludes Applicants from now claiming it as their own.

Also, that the present claims include the term “pharmaceutical” at line 1 does not define over the composition taught by the patentees because the composition taught by Landry et al. is a pharmaceutical composition, whether expressly disclosed or not.

Accordingly, claims 1-5, 28 and 29 remain properly rejected.

#### ***Claim Objection***

Claims 30-32 are objected to as depending from a rejected base claim, but are otherwise in condition for allowance. It remains the Examiner’s position that claims 30-31 are allowable over the teaching of Landry et al. for the reasons set forth in the previous Office action dated August 16, 2004 at pages 3-4, i.e., because the dosage amounts required by claims 30-31 are clearly above those that would have been in the reference compositions. Also, because S-tofisopam is not the active agent of the reference and is merely administered for comparative effects, no motivation is present to have altered the dosage amounts of S-tofisopam disclosed by the patentees.

Claim 32 is also deemed allowable. As presently amended, the claim requires that S-tofisopam, substantially free of its R-enantiomer, (required by present claim 1), is administered at a dosage of less than 30 mg/kg. Landry et al. teach the administration of S-tofisopam only at a dosage of 30 mg/kg which is above the required dosage of the claim. Also, because S-tofisopam is not the active agent of the reference and is merely administered for comparative effects, no motivation is present to have altered this dosage amount of S-tofisopam.

None of the claims are allowed.

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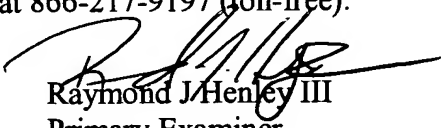
**THIS ACTION IS MADE FINAL.** Applicants are reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Raymond J. Henley III whose telephone number is 571-272-0575. The examiner can normally be reached on M-F, 8:30 am to 4:00 pm Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Raymond J. Henley III  
Primary Examiner  
Art Unit 1614

March 23, 2005